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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,452	01/10/2002	Masayuki Yabuta	58777.000002	5707

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,452	YABUTA ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/19/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final office action is in response to the paper filed on 10/19/2005.

Claims 3-6 and 8-12 are pending. Claims 1, 2, and 7 has been cancelled.

This application is 371 of PCT/JP01/03909, filed on 05/10/2001.

The Applicant claims priority to JAPAN 2000-137228, filed on 05/10/2000, but the priority documents are not on file. Thus, the Applicant must submit a copy of the priority documents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-6 and 8-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Yabuta et al. (U.S. 5,670,340).

The present invention is directed to a method of producing atrial natriuretic proteins in culture medium or broth that is supplemented with any one of the amino acids histidine, methionine and glycine.

Yabuta et al. teach a process of expression a target peptide in a large amount and accumulation of the target peptide in host cells in the form of occlusion bodies. See Abstract. In Examples 3 and 4 Yabuta et al. teach production of human calcitonin from

fusion protein in E.coli. Examples 5-8 teach production of CNP-22 from fusion protein in E.coli.

Yabuta et al. do not teach production of ANP from fusion protein in E.coli.

In column 4, line 20-26, Yabuta et al. state that the method can be applied for production of a fusion protein of physiologically active peptides, for example natriuretic peptides, such as ANP. In Claim 1, Yabuta et al. claim process for the production of a target peptide, where the target peptide can be ANP.

Therefore, it would have been obvious to a person of ordinary skill in the art to substitute ANP for human calcitonin or CNP as per teachings of Yabuta et al. because the same result should be expected when using ANP in place of CNP or clacitonin. It would be predictable that the method would work with ANP because Yabuta et al. showed that the method was successful with calcitonin and CNP, because Yabuta et al. stated that the same method would work for ANP.

One would be motivated to use ANP in place of calcitonin or CNP because the steps in the method disclosed by Yabuta et al. would be the same, and the expectation of success would be high because of the great results achieved by Yabuta et al.

Applicants stated that Yabuta fails to teach or suggest each of the three steps recited in the claimed methods because Yabuta does not teach or suggest the step of adding at least one of histidine, methionine or glycine to reduce byproduct formation or the step reducing the formation of said byproduct polypeptide; and that examiner fails to point out where Yabuta teaches or suggests all of the elements contained in the culture media of claims 11 or 12.

Examiner respectfully disagrees because still it would have been obvious to a person of ordinary skill in the art to substitute ANP for human calcitonin or CNP as per teachings of Yabuta et al. because the same result should be expected when using ANP in place of CNP or clacitonin. Yabuta teaches a process for the production of a protein (including atrial natriuretic peptide) comprising culturing E.coli host cells transformed with a plasmid capable of expressing the protein (see claim 1). The broth media used during the incubation or growth step of the host cell in E.coli comprises 2.9 g/L of L-methionine (see example 3), and thus both product and method are taught. Therefore, the rejection stands.

Claim 9 is rejected because the preamble states "*a method for reducing formation of a byproduct polypeptide comprising an o-acetylserine residue in place of a serine residue, comprising..*" however the invention only requires culturing transformed host cells in a medium comprising at least one histidine, methionine or glycine in an effective amount to reduce the formation of a byproduct polypeptide. The recitation of o-acetylserine is limited to the preamble of the claims or as the inherent end-point of the claimed method. *In re Hirao*, 535, F.2d 67, 190 USPQ 15 (CCPA 1976), the court states that a preamble is generally not accorder any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness, but instead, the process steps or structural limitation are able to stand alone.

Applicants state that contrary to the Office Action's assertion that "the invention only requires culturing transformed host cells in a medium comprising at least one histidine, methionine or glycine.." claim 9 recites three method steps; and that contrary to the Office Action's assertion that "the recitation of o-acetylserine is limited to the preamble of the claims or as the inherent end-point of the claimed method," step (1) of claim 9 recited "culturing, in a medium, transformed host cells that produce....a byproduct polypeptide comprising an o-acetylserine residue in place of a serine residue and step (iii) recited "reducing the formation of said byproduct polypeptide." Thus, Applicants state that the Office Action improperly limits claim 9.

Examiner responds that recitation of o-acetylserine is limited to the preamble of the claims or as the inherent end-point of the claimed method. Therefore, the rejection stands.

In Claims 10-12, the Applicant claims o-acetylserine as a byproduct formed in the method of production of an atrial natriuretic peptide comprising a serine residue.

MPEP section 2105 states that language that suggests or makes optional, but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. For example, a language that may raise a question as to the limiting effect of the language in a claim are statements of intended use or field of use. In claims 10-12, the byproduct o-acetylserine has no effect on the steps performed in the method, therefore o-acetylserine does not limit the claims.

Therefore, it would have been obvious to one skilled in the art to design a method for the production of a protein comprising culturing E.coli host cells transformed with a plasmid capable of expressing the protein, where the protein produced is the human atrial natriuretic peptide as suggested by Yabuta et al., and where the byproduct formed is in a form of o-acetyl-serine. One would be motivated to produce the atrial natriuretic peptides because of the success of the method in producing a human calcitonin as taught by Yabuta et al.

Applicants state that MPEP section 2105 does not state or provide any discussion regarding "language that suggests or makes optional, but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation."

Examiner states that the MPEP section 2105 is applicable to this rejection because o-acetylserine is a byproduct formed in the method and it is not required in the step to be performed and does not limit the claim to a particular structure. Therefore, the rejection stands.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-273-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

ROBERT A. WAX
PRIMARY EXAMINER